

## **REMARKS/ARGUMENTS**

By the foregoing amendment, the Abstract has been amended to meet the current 150 word limit and claims 1 and 16 have been amended solely to clarify the claimed subject matter. No new matter has been added. Reconsideration is respectfully requested.

### **Objection to Specification**

In the Office Action, the abstract was objected to on grounds that it contained more than 150 words. By the foregoing amendment, the abstract has been reduced to 128 words. No new matter has been added. Accordingly, the stated objection to the specification has been overcome.

### **35 U.S.C. §102 Rejections**

In the Office Action, claims 1, 3-9, 12, 14 and 15 were rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 3,789,837 (Phillips et al.). Applicants respectfully traverse this rejection.

Phillips et al. describes a ventilator that incorporates a spirometer (item 116 on Phillips et al. Figure 1). The examiner contends in the Office Action that the spirometer 116 of Phillips et al. comprises “a chamber, which contains a volume of oxygen contained within the chamber, the spirometric device being connected to the ventilation circuit such that the volume of oxygen contained in the chamber will vary relative to the volume of oxygen taken up by the patient.” Applicants disagree with this reading of Phillips et al. In fact, as explained in more detail below, the spirometer 116 of Phillips et al. does not determine oxygen uptake and Phillips et al. makes no suggestion that his spirometer 116 could be used to determine oxygen uptake.

As presently amended, independent claims 1 recites a system that includes a spirometric device comprising a chamber within which a volume of oxygen is contained and an indicator for indicating changes in the volume of oxygen contained within the chamber. Claim 1 additionally requires the spirometric device to be connected to the expiratory flow conduit of the ventilation circuit such that the volume of oxygen contained in the chamber will decrease by a volume that is equivalent to the volume of oxygen taken up by the patient.

The spirometer 116 of Phillips et al. does not contain oxygen and it is not used to measure oxygen uptake in any way. Rather, the spirometer 116 of Phillips et al. incorporates bellows 118 which receives the patient's "exhaled breath." This bellows 118 is then compressed "to ensure that the exhaled breath leaves the spirometer before the next breath begins to enter the spirometer." (Column 4, lines 66-68) Thus, in the Phillips et al. device, the spirometer 116 receives and expels exhaled breath. This is clearly different from Applicant's invention wherein the patient's "exhaled breath" does not enter the spirometer. Rather, in Applicants' system, the spirometric device is filled with oxygen and the oxygen flows out of the spirometer and becomes mixed with expired gasses flowing through the expiration conduit to make up for oxygen that has been taken up by the patient's body. The volume of oxygen that exits Applicants' spirometer chamber is equivalent to the volume of oxygen that has been taken up by the patient's body. Applicants' system includes means for measuring this change in oxygen volume within the spirometer chamber. Thus, Applicants' oxygen uptake measuring system differs substantially from the system described by Phillips et al.

For these reasons and possibly others not specifically stated here, the invention recited in independent claim 1 (and dependent claims 3-9, 12, 14 and 15) is clearly distinguishable over Phillips et al. and the stated rejection under 35 U.S.C. §102(b) is not sustainable.

35 U.S.C. §103 Rejections

*A. Rejection of Claims 10, 11 and 16-22 Over Phillips et al. Alone*

In the Office Action, claims 10, 11 and 16-22 were rejected under 35 U.S.C. §103(a) as being obvious over Phillips et al.

Claims 10 and 11 depend from claim 1 and are distinguishable over Phillips et al. for the same reasons stated above with respect to claim 1. Phillips et al. does not even remotely suggest the system recited in any of Applicant's claims 1-15.

Claims 16-22 are directed to a method for determining oxygen uptake in a human or veterinary patient. As presently amended, independent method claim 16 requires the use of a spirometric device having a chamber which contains a volume of oxygen and an indicator for indicating changes in the volume of oxygen contained within the chamber. Independent method

claim 16 further requires the spirometric device to be connected to the expiratory flow conduit such that the volume of oxygen contained in the chamber of the spirometric device will decrease by a volume that is equivalent to the volume of oxygen taken up by the patient. This is in stark contrast to the method described by Phillips et al. wherein the spirometer 116 merely receives and expels expired air and does not function to measure oxygen uptake in any way. Thus, independent claim 16 (and dependent claims 17-22) are non-obvious over Phillips et al. for at least the same reasons as stated above with respect to claim 1.

*B. Rejection of Claim 2 Over Phillips et al. in View of Smargiassi et al.*

Also in the Office Action, dependent claim 2 was rejected over Phillips et al. (as applied to claim 1) in view of United States Patent No. 4,727,871 (Smargiassi et al.).

Dependent claim 2 incorporates all of the limitations of independent claim 1 and further requires the inclusion of a carbon dioxide absorber connected to the system such that gas from the expiratory flow conduit will pass through the carbon dioxide absorber where carbon dioxide will be removed from the gas.

Smargiassi et al. describes an exhalation system for connection in the exhalation path of a ventilator. In the Office Action, the Examiner contends that “Smargiassi teaches an apparatus that does provide a carbon dioxide absorber 18 connected to the system such that gas from the expiratory flow circuit will pass through the carbon dioxide absorber where carbon dioxide will be removed from the gas...” This is untrue. Item 18 of the Smargiassi et al. system is a “water trap” not a carbon dioxide absorber.

Furthermore, Smargiassi et al. contains nothing to remedy the fundamental shortcoming of the primary reference, Phillips et al. (i.e., the fact that the spirometer of Phillips et al. a) is not filled with oxygen, b) does not lose a volume of oxygen that is equal to the volume of oxygen taken up by the patient and c) cannot be used to measure oxygen uptake).

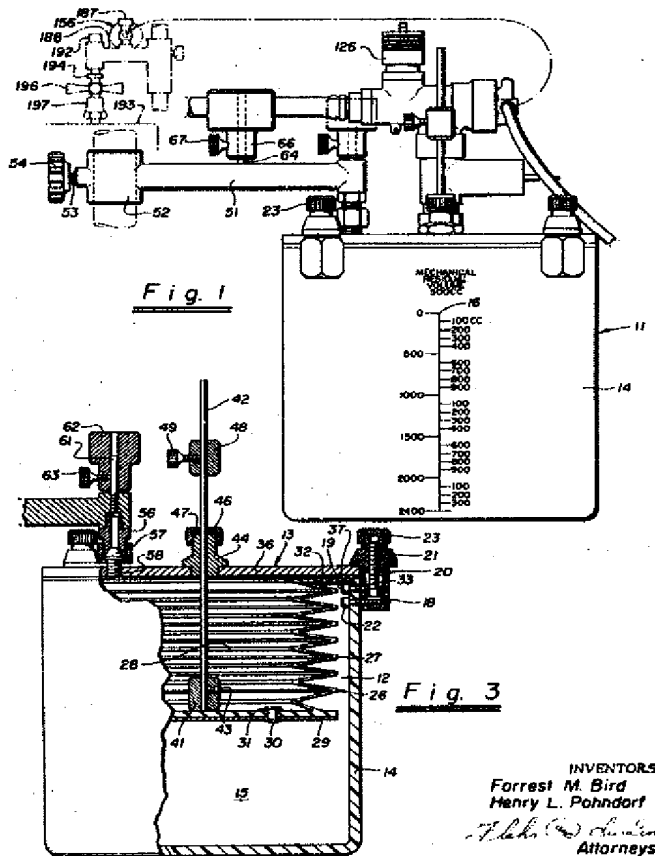
Thus, neither Phillips et al. nor Smargiassi et al., taken alone or in combination, even remotely suggest the invention recited in claim 2. Withdrawal of this rejection is requested.

D. *Rejection of Claim 13 Over Phillips et al. in View of Bird et al.*

Additionally, in the Office Action, claim 13 was rejected over Phillips et al. (as applied to claim 1) in view of United States Patent No. 3,467,078 (Bird et al.).

Dependent claim 13 incorporates all of the limitations of independent claim 1 and further requires 1) that the chamber of the spirometric device be adapted to move in relation to the volume of oxygen contained within the chamber and 2) that the indicator for indicating changes in the volume of oxygen contained within the chamber comprise a scale marked on the chamber to indicate the distance by which the chamber has moved.

As shown in Figures 1 and 3 of Bird et al. (reproduced below), Bird et al. describes a spirometer device that comprises a transparent container 14 having a bellows 12 disposed within the transparent container 14. The bellows received and expels expired gasses from the patient. Vertical calibrations 16 are provided on the transparent container 14 to enable one to determine the volume of gas contained within the bellows 12.



The bellows 12 of the Bird et al. devices does move as it receives and expels expired air. However, it is not filled with oxygen as in Applicants' claimed invention and, as with the spirometer of Phillips et al., it does not measure oxygen uptake in any way. Thus, the vertical calibrations 16 on the transparent container 14 are not used to measure oxygen volume as required of Applicants' claim 13, but merely measure the volume of expired gases contained in the bellows 12 at any given time.

Furthermore, Bird et al. contains nothing to remedy the fundamental shortcoming of the primary reference, Phillips et al. (i.e., the fact that the spirometer of Phillips et al. a) is not filled with oxygen, b) does not lose a volume of oxygen that is equal to the volume of oxygen taken up by the patient and c) cannot be used to measure oxygen uptake).

Thus, neither Phillips et al. nor Bird et al., taken alone or in combination, even remotely suggest the invention recited in claim 13. Withdrawal of this rejection is requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and issuance of a notice of allowance is earnestly solicited.

A one (1) month extension is hereby petitioned for pursuant to 37 C.F.R. 1.136 and the Commissioner is hereby authorized to deduct the small entity fee for such extension, as well as any other fee properly deemed to be due in connection with the filing of this paper, from Deposit Account No. 50-0878. The Examiner is invited to telephone Applicant's undersigned counsel to discuss any further measures that may be taken to .

Respectfully submitted,

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